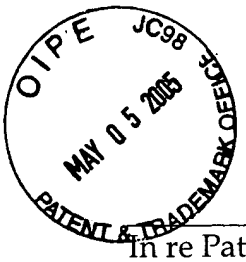

Docket No.: 3868-0160PUS1
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Joachim MOORMANN et al.

Application No.: 10/523,012 Confirmation No.: 7480

Filed: February 1, 2005 Art Unit: 1645

For: MEDICAMENT AND METHOD FOR REDUCING ALCOHOL AND/OR TOBACCO CONSUMPTION Examiner: Not Yet Assigned

LETTER

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Subsequent to the filing of the above-identified application on February 1, 2005, attached hereto is an English translation of the International Preliminary Examination Report (Form PCT/IPEA/409) that should be made of record in the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or to credit any overpayment to Deposit Account No.

02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Dated: 5-5-05

Respectfully submitted,

By _____

James M. Slattery

Registration No.: 28,380

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Attachment(s)

Translation

PCT/EP2003/008236

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference HF 001/2002 PCT	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/EP2003/008236	International filing date (*day/month/year*) 25 July 2003 (25.07.2003)	Priority date (*day/month/year*) 03 August 2002 (03.08.2002)
International Patent Classification (IPC) or national classification and IPC A61K 31/5513		
Applicant HF ARZNEIMITTELFORSCHUNG GMBH		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 8 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 1 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
22 January 2004 (22.01.2004)	07 December 2004 (07.12.2004)
Name and mailing address of the IPEA/EP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/EP2003/008236

I. Basis of the report

1. With regard to the **elements** of the international application:*

☐ the international application as originally filed

☒ the description:

pages 1-12, as originally filed

pages _____, filed with the demand

pages _____, filed with the letter of _____

☒ the claims:

pages 5 (in part), 6-19, as originally filed

pages _____, as amended (together with any statement under Article 19

pages _____, filed with the demand

pages 1-4, 5 (in part) (with the fax of 03.05.04), filed with the letter of _____

☐ the drawings:

pages _____, as originally filed

pages _____, filed with the demand

pages _____, filed with the letter of _____

☐ the sequence listing part of the description:

pages _____, as originally filed

pages _____, filed with the demand

pages _____, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/EP2003/008236

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 10-19 (IA)

because:

☒ the said international application, or the said claims Nos. 10-19 (IA) relate to the following subject matter which does not require an international preliminary examination *(specify)*:

See supplemental sheet

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. _____ are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for said claims Nos. _____.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

I. **Basis of the report**

1. This report has been drawn on the basis of *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.)*:

The examination is based on claims 1-4 and 5 (in part) submitted with the fax message of 3 May 2004, the original claims 5 (in part) to 19, and pages 1-12 of the description as originally filed.

PCT Article 34(2)(b)

The amendments submitted with the fax message referred to above do not introduce any substantive matter which, contrary to PCT Article 34(2)(b), goes beyond the disclosure in the international application as filed. Especially paragraph 2 on page 5, pages 6-8, which specify the various suitable administration forms, and paragraph 3 on page 11, indicate that the application concerns administration forms which can be administered separately.

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: III.1

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Claims 10-19 refer to a subject matter which, in the opinion of the Examining Authority, falls under PCT Rule 67.1(iv). Consequently, no opinion is established with regard to the industrial applicability of the subject matter of these claims (PCT Article 34(4)(a)(i)).

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

[redacted]ational application No.
PCT/EP 03/08236

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	3-5, 8-19	YES
	Claims	1, 2, 6, 7	NO
Inventive step (IS)	Claims		YES
	Claims	1-19	NO
Industrial applicability (IA)	Claims	1-9	YES
	Claims		NO

2. Citations and explanations

Reference is made to the following documents:

D1: WO 00 38686 A (CONDE VALENTIN FLORENT VICTOR; GILIS PAUL MARIE VICTOR (BE); MCGEE) 6 July 2000 (2000-07-06)

D2: OPITZ K: 'Tobacco dependence and remedies for withdrawal' PHARMAZEUTISCHE ZEITUNG 1996 GERMANY, Vol. 141, No. 26, 1996, pages 46-48, XP001155945 ISSN: 0031-7136

D3: DE 43 01 782 C (LOHMANN THERAPIE SYST LTS; HF ARZNEIMITTELFORSCH GMBH (DE)) 25 August 1994 (1994-08-25)

D4: WO 97 47304 A (CONDE VALENTIN FLORENT VICTOR; GILIS PAUL MARIE VICTOR (BE); JANSS) 18 December 1997 (1997-12-18)

D5: US-A-5 589 475 (SNORRASON ERNIR) 31 December 1996 (1996-12-31).

Explicit reference is made to the relevant passages only if these were not already specified in the international search report.

PCT Article 33(2)

The present application does not meet the requirements of PCT Article 33(2) because the subject matter of claims 1, 2, 6 and 7 is not novel.

Document D1 discloses a medical drug containing galanthamine in a sustained release administration form (sustained release pellets) and in an immediate release administration form (immediate release mini-tablets). Even though both administration forms would first have to be removed from the capsule, they can in principle be administered separately.

Since for the establishment of an opinion with regard to novelty the wording of a claim has to be interpreted as broadly as possible, the subject matter of claims 1, 2, 6 and 7 would appear not to be novel in the light of document D1.

PCT Article 33(3)

The present application does not meet the requirements of PCT Article 33(3) because the subject matter of claims 1-19 appears not to be inventive.

Document D2 is the closest prior art. Its teaching indicates that during tobacco withdrawal the combination of two different administration forms (TTS and buccal administration, that is, they can be administered independently of each other) is desirable so as to be able to control the supply of the withdrawal agent in accordance with need (see in particular the last paragraph on page 48). In the examiner's opinion, "on demand

control" during a tobacco withdrawal treatment, as described in document D2, implies the "on demand" administration of the medical drug as soon as a craving for the substance arises (= need). This opinion is supported by paragraph 1, central column, on page 47 ("Nicotine substitution ... permits users to control their nicotine supply depending on the situation in which they find themselves; for instance, more nicotine in stressful situations"), in which the use in a breakdown situation (stress) typical for nicotine addicts is cited.

The problem to be solved can therefore be defined as follows:

to find a new combination of two different administration forms containing a withdrawal agent. The present application suggests the use of galanthamine as a withdrawal agent to solve the stated problem. The administration forms of the claimed combination, which each contain galanthamine, are known from the teachings of documents D3, D4 and D5 for the treatment of alcoholism and smoking cessation.

In the light of the teaching of the prior art the following is noted:

as regards the subject matter of claims 1, 2, 6 and 7, the applicant is reminded that even if they were to be found to be novel with respect to the above prior art, the present application still appears to contain no basis for an inventive step of said claims.

As regards the subject matter of claims 3-5 and 8-19, the present application appears to contain nothing on the basis of which an inventive step might be recognized,

since at present there appears to be no proof that the technical features establishing novelty contribute to a solution of the problem of interest which would not have been obvious to a person skilled in the art. In the light of the teaching of document D1, which recommends a combination of administration forms which release withdrawal agents in both a sustained and a rapid manner, the person skilled in the art randomly selected known administration forms with an active substance known to be suitable for achieving the above therapeutic effect. Since this selection does not appear to have a surprising effect, the subject matter of claims 3-5 and 8-19 appears not to be inventive within the meaning of PCT Article 33(3).

PCT Article 33(4)

The subject matter of claims 1-9 is considered industrially applicable within the meaning of PCT Article 33(4).

The PCT Contracting States do not have uniform criteria for assessing the industrial applicability of claims 10-19 in their present form. Patentability may also depend on the wording of the claims. The EPO, for example, does not recognize the industrial applicability of claims to the medical use of a compound; it may, however, allow claims to the first medical application of a known compound or to the use of such a compound in the manufacture of a drug for a new medical application.